

AMENDED IN SENATE MARCH 30, 2006

SENATE BILL

No. 1763

Introduced by ~~Senator Figueroa~~ *Senators Figueroa and Kuehl*

February 24, 2006

~~An act relating to pharmaceuticals.~~ *An act to add Division 112.7 (commencing with Section 130675) to the Health and Safety Code, relating to compulsory licensing of pharmaceutical drugs.*

LEGISLATIVE COUNSEL'S DIGEST

SB 1763, as amended, Figueroa. Pharmaceuticals: compulsory licensing.

Under existing law, the State Department of Health Services administers the Medi-Cal program, and is authorized, among other things, to enter into contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufacturers are required to calculate and pay interest on late or unpaid rebates.

~~This bill would declare the intent of the Legislature to enact legislation to establish a process by which the state may authorize compulsory licensing of pharmaceuticals.~~

This bill would authorize the Governor to issue a declaration of necessity for compulsory licensing of pharmaceuticals if specified conditions are met. The bill would also authorize the department to issue a license for the manufacture of the pharmaceutical drug described in the declaration of necessity, and include other related provisions.

Vote: majority. Appropriation: no. Fiscal committee: ~~no~~-yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature finds and declares all of the
2 following:

3 (a) The World Health Organization has recommended that
4 governments stockpile antiviral drugs to limit the spread of a
5 potential influenza pandemic.

6 (b) The Infectious Disease Society of America has advocated
7 that the federal government stockpile sufficient medicines to treat
8 25 to 40 percent of the population of the United States.

9 (c) The United States has fallen far short of achieving the
10 President's goal of stockpiling enough antiviral medications to
11 treat 81 million individuals in the event of a flu pandemic, with
12 the current stockpile at approximately 4.3 million courses.

13 (d) There is question as to the ability of existing
14 pharmaceutical manufacturers to produce sufficient supplies of
15 antiviral medications in a near-term time frame to meet the
16 treatment goals recommended.

17 (e) Voluntary or compulsory licensing to manufacturers other
18 than existing rights holders can be used to produce generic
19 versions of needed medications in a health emergency, such as
20 the antiviral medications needed to limit the spread of a potential
21 influenza pandemic.

22 (f) Compulsory licensing is used in other industries in the
23 United States.

24 (g) There is federal statutory authority to authorize the federal
25 government to use compulsory licensing in the pharmaceutical
26 industry.

27 (h) The World Trade Organization allows countries to issue
28 compulsory licenses for pharmaceuticals to address public health
29 needs.

30 (i) Compulsory licensing could be used by the state to ensure
31 sufficient production of needed medications in a health
32 emergency, with reasonable compensation to the rights holder, if
33 voluntary licenses are insufficient to meet public health needs.

34 ~~SEC. 2. It is the intent of the Legislature to enact legislation~~
35 ~~establishing a process by which the state may issue a compulsory~~
36 ~~license, with reasonable compensation to the rights holder, to~~
37 ~~ensure that the state obtains needed medications in a public~~
38 ~~health emergency.~~

1 *SEC. 2. Division 112.7 (commencing with Section 130675) is*
2 *added to the Health and Safety Code, to read:*

3
4 *DIVISION 112.7. COMPULSORY LICENSING OF*
5 *PHARMACEUTICAL DRUGS*
6

7 130675. *For purposes of this division, the following*
8 *definitions shall apply:*

9 (a) *“Department” means the State Department of Health*
10 *Services.*

11 (b) *“Use by the state” means the provision of a*
12 *pharmaceutical drug subject to the license allowed pursuant to*
13 *this division to an individual for whom the state provides*
14 *financial payment or assistance for health benefits, including*
15 *state employees, beneficiaries of Medical, beneficiaries of*
16 *Medi-Cal, and other state pharmacy programs, individuals under*
17 *the supervision of the Department of Corrections and*
18 *Rehabilitation, free health clinics, and beneficiaries of workers’*
19 *compensation.*

20 130676. (a) *The Governor may issue a declaration of*
21 *necessity for compulsory licensing pursuant to this division to*
22 *address a public health emergency.*

23 (b) *The declaration of necessity for compulsory licensing shall*
24 *include all of the following:*

25 (1) *The public health and safety basis for issuing the license to*
26 *manufacture, which may consider whether adequate access to a*
27 *pharmaceutical is essential for maintaining health or life.*

28 (2) *A list of the relevant patents, exclusive marketing periods,*
29 *copyrights, trademarks, and any other relevant property to be*
30 *licensed under this division.*

31 (3) *The proposed license, including royalty rate.*

32 (c) *The department shall establish a process to notify the*
33 *public of the declaration of necessity and to disseminate*
34 *information to pharmacists, local public health officers, and any*
35 *other individuals or groups, as deemed necessary by the*
36 *department.*

37 (d) *The notice of the declaration of necessity and a copy*
38 *thereof shall be sent to the registered agent in the state of*
39 *incorporation of each company that may be affected by the*

1 *licensing within five days of the declaration of necessity being*
2 *published in one newspaper.*

3 *(e) The licensure process shall be conducted by the*
4 *department.*

5 *130676. (a) The department shall establish a process to*
6 *permit any person affected by the compulsory licensing may*
7 *appeal the licensure of the property listed in the declaration.*

8 *(b) If no notice of intervention is filed, the department may*
9 *issue the license pursuant to Section 130677.*

10 *130677. (a) If the requirements of Sections 130675 and*
11 *130676 are met, the department may issue a license for the*
12 *manufacture of the pharmaceutical drug described in the*
13 *declaration of necessity. In addition the department shall notify*
14 *the owner of the property being licensed of the amount of just*
15 *compensation and any terms or conditions contained in the*
16 *opinion of the department after the expiration of the appeal*
17 *period.*

18 *(b) The department may assign the license to one or more*
19 *manufacturers of pharmaceutical drugs solely for the*
20 *manufacture of the pharmaceutical drug for the use by the state*
21 *and other states that have issued substantially similar licenses.*

22 *130678. Nothing in this division shall operate as a waiver of*
23 *the state's sovereign immunity.*